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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Mohammad A. Heidaran et al.

Attorney Docket No.: DEYP014

Application No.: 09/805,816

Examiner: Liliana Di Nola-Baron

Filed: March 13, 2001

Group: 1615

D/K to
enter

Title: METHOD OF INDUCING OR
ENHANCING CHONDROGENESIS WITH
EXTRACELLULAR MATRIX
CONTAINING BMP-4

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first-class mail on June 4, 2003 in an envelope addressed to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

Signed: _____

Joyce L. Ferreira

RESPONSE TO FINAL REJECTION

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a response to the final rejection of March 12, 2003. A response is due by June 12, 2003.

Please cancel claims 12-19 without prejudice to applicant's right to file a continuing application directed to that subject matter.

Claims 1-4, 6-11, and 20-23 are pending in the application. Claims 7, 9 and 11 are objected to. Claims 1-23 are rejected.

Claims 7, 9, and 11 are objected to under 35 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Withdrawal of this objection is respectfully requested. The Examiner states that claims 7, 9 and 11 read on a method according to claims 21, 22, or 23 which are independent claims directed to methods for inducing or enhancing chondrogenesis in cells. Claims 7 and 9 further limit the method by explaining that the cells are either in vivo, that is in a living animal or human, or in vitro, such as in a culture dish. Claim 11 further recites that the cells are joint tissues, which further narrows

claim 7. Thus, the dependent claims 7, 9 and 11 certainly further limit the independent claims 20, 21, 22 and 23 from which they depend and are proper under 37 CFR 1.75(c). It is noted that the Examiner states that the claims objected to do not limit the subject matter of a "previous" claim. If it is the Examiner's view that claims 7, 9, and 11 refer to higher numbered claims, that is not claims numbered less than 7, it is submitted that that is not the intent of rule 37 CFR 1.75(c). Indeed the rule does not use the word "previous". The rule states that one or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. The rule does not require that the numbering of the dependent claims be higher than those of the claims from which they depend.

Claims 1-23 are rejected under 35 USC 102(e) as allegedly being anticipated by Heidaran et al. ("Heidaran"), of record. This rejection is respectfully traversed. The Examiner states that Heidaran discloses collagen-polysaccharide matrices, and preferably collagen-hyaluronic acid matrices containing BMP's and GDF's for the treatment of bone tumors, including the use of type I or type II collagen. The Examiner further states that Heidaran defines "repair" as growth of new tissue. It is first pointed out that Heidaran also defines "treatment of bone tumor" and that definition does not recite anything about growth of new tissue. Furthermore, new tissue does not necessarily mean cartilage and there is no teaching anywhere of new cartilage growth using the BMP's in Heidaran. On the other hand, according to the present invention the use is for chondrogenesis which is the development of cartilage. It is not seen how use of a material of the treatment of bone tumor, which does not explicitly include growth of new cartilage can anticipate a method of growing new cartilage. Indeed Heidaran states in column 2, lines 3-7, that the growth factor in question has an unexpected potent anti-growth property used without soluble collagen. It is therefore requested that this rejection be withdrawn.

Claims 1-4 and 12-15 are rejected under 35 USC 102(e) as allegedly being anticipated by Hattersley, et al. ("Hattersley"), of record. This rejection is respectfully traversed. Hattersley discloses compositions containing proteins which are useful for the induction of cartilaginous tissue formation. The compositions require the presence of a BMP-12 related subfamily of proteins for the induction of cartilaginous tissue. Optionally, the composition may contain one or more osteogenic proteins which are TGF- β 's or BMP's, including, BMP-4. However, the osteogenic proteins are not taught as inducing new growth of cartilage. See Example 2 which directly proves this point. In Example 2, BMP-13, the cartilage inducing protein alone, is shown to induce chondroblast or cartilaginous tissue, but the osteogenic protein alone, BMP-2, results in

an expression of bone phenotypes. Example 4 further confirms this point. At column 11, line 16 it is stated:

Thirty percent of the defects containing rhBMP-13 had an organization of chondrocytes in the repair cartilage similar to normal hyaline articular cartilage radial zone architecture, a phenotype not seen with rhBMP-2 treatment at 4 weeks.

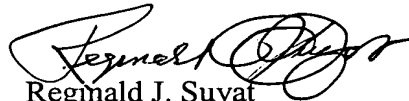
The other examples 5, 6, and 7 further prove that the BMP-13 is necessary for chondrocyte differentiation, a critical step in inducing cartilage. The other osteogenic BMP's, such as BMP-2, if present, are preferred for maintenance of the tissues, but cannot differentiate chondrocytic cells.

Therefore it is submitted that the teaching of Hattersley is that no amount of one of the osteogenic proteins, such as BMP-2 or BMP-4, can differentiate chondrocytes, that is, induce cartilage formation. It can only produce bone or, if present in combination with BMP-13, help to maintain the cartilage induced by BMP-13. Therefore the language in applicant's claims of "an effective amount of BMP-4 sufficient to induce or enhance chondrogenesis" is not anticipated by Hattersley since according to Hattersley there can never be an effective amount of BMP-4 sufficient to induce or enhance chondrogenesis, even if BMP-13 is present. The teaching of Hattersley is that it is the BMP-13 that is inducing or enhancing chondrogenesis. Accordingly, it is submitted that Hattersley does anticipate the claimed invention and withdrawal of the rejection is respectfully requested.

Claims 12-19 are rejected on 35 USC 103(a) as allegedly being unpatentable over Adams et al. ("Adams"), of record. The rejection is moot. For the foregoing reasons it is submitted that the application is in condition for allowance.

Respectfully submitted,

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